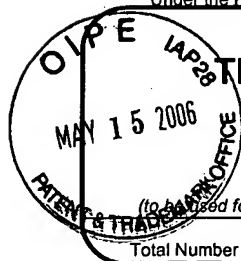


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# TRANSMITTAL FORM

(To be used for all correspondence after initial filing)

Total Number of Pages in This Submission

Application Number	10/559,882
Filing Date	December 7, 2005
First Named Inventor	Prasch et al.
Art Unit	1615
Examiner Name	Not Yet Known
Attorney Docket Number	SMB-PT164 (PC 04 246 K US)

## ENCLOSURES (Check all that apply)

<input type="checkbox"/> Fee Transmittal Form <input type="checkbox"/> Fee Attached <input type="checkbox"/> Amendment/Reply <input type="checkbox"/> After Final <input type="checkbox"/> Affidavits/declaration(s) <input type="checkbox"/> Extension of Time Request <input type="checkbox"/> Express Abandonment Request <input type="checkbox"/> Information Disclosure Statement  <input type="checkbox"/> Certified Copy of Priority Document(s) <input type="checkbox"/> Reply to Missing Parts/Incomplete Application <input type="checkbox"/> Reply to Missing Parts under 37 CFR 1.52 or 1.53	<input type="checkbox"/> Drawing(s) <input type="checkbox"/> Licensing-related Papers <input type="checkbox"/> Petition <input type="checkbox"/> Petition to Convert to a Provisional Application <input type="checkbox"/> Power of Attorney, Revocation <input type="checkbox"/> Change of Correspondence Address <input type="checkbox"/> Terminal Disclaimer <input type="checkbox"/> Request for Refund <input type="checkbox"/> CD, Number of CD(s) _____ <input type="checkbox"/> Landscape Table on CD	<input type="checkbox"/> After Allowance Communication to TC <input type="checkbox"/> Appeal Communication to Board of Appeals and Interferences <input type="checkbox"/> Appeal Communication to TC (Appeal Notice, Brief, Reply Brief) <input type="checkbox"/> Proprietary Information <input type="checkbox"/> Status Letter <input checked="" type="checkbox"/> Other Enclosure(s) (please identify below): <b>International Preliminary Report on Patentability</b>
<div>Remarks</div>		

## SIGNATURE OF APPLICANT, ATTORNEY, OR AGENT

Firm Name	VOLPE AND KOENIG, P.C.		
Signature			
Printed name	Randolph J. Huis		
Date	5/12/2006	Reg. No.	34,626

## CERTIFICATE OF TRANSMISSION/MAILING

I hereby certify that this correspondence is being facsimile transmitted to the USPTO or deposited with the United States Postal Service with sufficient postage as first class mail in an envelope addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on the date shown below:

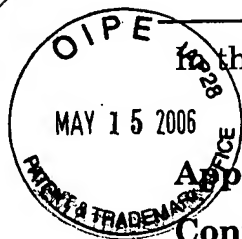
Signature			
Typed or printed name	Randolph J. Huis	Date	5/12/2006

This collection of information is required by 37 CFR 1.5. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.11 and 1.14. This collection is estimated to 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

If you need assistance in completing the form, call 1-800-PTO-9199 and select option 2.

**PATENT**

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**



In the **PATENT APPLICATION** of:

Prasch et al.

**Application No.:** 10/559,882

**Confirmation No.:** 2925

**Filed:** December 7, 2005

**For:** MICROPELLETS, METHOD FOR THE  
PRODUCTION THEREOF, AND USE  
THEREOF

**Group:** 1615

**Examiner:** Not Yet Known

**Our File:** SMB-PT164  
(PC 04 246 K US)  
**Date:** March 23, 2006

**COMMUNICATION RE  
INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY**

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Sir:

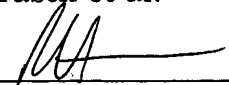
Enclosed is the English language translation of the International Preliminary Report on Patentability related to the above-identified 35 U.S.C. §371 National Phase Application based on PCT/EP2004/005993.

Prompt examination of the present application is respectfully requested.

Respectfully submitted,

Prasch et al.

By

  
Randolph J. Huis  
Registration No. 34,626  
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RJH/dmm

**Translation**

# PATENT COOPERATION TREATY

## PCT

### INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

(Chapter II of the Patent Cooperation Treaty)

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference <b>PC 04 246 K</b>	FOR FURTHER ACTION See Form PCT/IPEA/416	
International application No <b>PCT/EP2004/005993</b>	International filing date (day/month/year) <b>03.06.2004</b>	Priority date (day/month/year) <b>07.06.2003</b>
International Patent Classification (IPC) or national classification and IPC <b>B01J2/16, A61 K31/7048</b>		
Applicant <b>GLATT GMBH</b>		

1 This report is the international preliminary examination report, established by this International Preliminary Examining Authority under Article 35 and transmitted to the applicant according to Article 36.

2 This REPORT consists of a total of 4 sheets, including this cover sheet.

3 This report is also accompanied by ANNEXES, comprising:

a. ☐ (sent to the applicant and to the International Bureau) a total of \_\_\_\_\_ sheets, as follows:

☐ sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications authorized by this Authority (see Rule 70.1b and Section 607 of the Administrative Instructions)

☐ sheets which supersede earlier sheets, but which this Authority considers contain an amendment that goes beyond the disclosure in the international application as filed, as indicated in item 4 of Box No. I and the Supplemental Box.

b. ☐ (sent to the International Bureau only) a total of (indicate type and number of electronic carrier(s)) \_\_\_\_\_ containing a sequence listing and/or tables related thereto, in computer readable form only, as indicated in the Supplemental Box Relating to Sequence Listing (see Section 802 of the Administrative Instructions)

4. This report contains indications relating to the following items:

<input checked="" type="checkbox"/>	Box No. I	Basis of the report
<input type="checkbox"/>	Box No. II	Priority
<input type="checkbox"/>	Box No. III	Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
<input type="checkbox"/>	Box No. IV	Lack of unity of invention
<input checked="" type="checkbox"/>	Box No. V	Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
<input type="checkbox"/>	Box No. VI	Certain documents cited
<input type="checkbox"/>	Box No. VII	Certain defects in the international application
<input type="checkbox"/>	Box No. VIII	Certain observations on the international application

Date of submission of the demand	Date of completion of this report
Name and mailing address of the IPEA/EP	Authorized officer
Facsimile No.	Telephone No.

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## INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No

PCT/EP2004/005993

## Box No. 1 Basis of the report

1 With regard to the language, this report is based on the international application in the language in which it was filed, unless otherwise indicated under this item.

- ☐ This report is based on translations from the original language into the following language \_\_\_\_\_ which is the language of a translation furnished for the purposes of:
- ☐ international search (Rule 12.3 and 23.1(b))
  - ☐ publication of the international application (Rule 12.4)
  - ☐ international preliminary examination (Rule 55.2 and/or 55.3)

2. With regard to the elements of the international application, this report is based on (replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 1-4 are referred to in this report as "originally filed" and are not annexed to this report):

☐ the international application as originally filed/furnished

☒ the description:

pages 1-20 \_\_\_\_\_ as originally filed/furnished

pages\* \_\_\_\_\_ received by this Authority on \_\_\_\_\_

pages\* \_\_\_\_\_ received by this Authority on \_\_\_\_\_

☒ the claims:

nos. 1-20 \_\_\_\_\_ as originally filed/furnished

nos. \* \_\_\_\_\_ as amended (together with any statement) under Article 19

nos. \* \_\_\_\_\_ received by this Authority on \_\_\_\_\_

nos. \* \_\_\_\_\_ received by this Authority on \_\_\_\_\_

☒ the drawings:

sheets 1/1 \_\_\_\_\_ as originally filed/furnished

sheets\* \_\_\_\_\_ received by this Authority on \_\_\_\_\_

sheets\* \_\_\_\_\_ received by this Authority on \_\_\_\_\_

☐ a sequence listing and/or any related table(s) - see Supplemental Box Relating to Sequence Listing.

3. ☐ The amendments have resulted in the cancellation of:

☐ the description, pages \_\_\_\_\_

☐ the claims, nos. \_\_\_\_\_

☐ the drawings, sheets/figs \_\_\_\_\_

☐ the sequence listing (specify): \_\_\_\_\_

☐ any table(s) related to sequence listing (specify): \_\_\_\_\_

4. ☐ This report has been established as if (some of) the amendments annexed to this report and listed below had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).

☐ the description, pages \_\_\_\_\_

☐ the claims, nos. \_\_\_\_\_

☐ the drawings, sheets/figs \_\_\_\_\_

☐ the sequence listing (specify): \_\_\_\_\_

☐ any table(s) related to sequence listing (specify): \_\_\_\_\_

\* If item 4 applies, some or all of those sheets may be marked "superseded."

## INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No.

PCT/EP2004/005993

Box No. V	Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement		
<b>1. Statement</b>			
Novelty (N)	Claims	1-20	YES
	Claims		NO
Inventive step (IS)	Claims	11-14, 16, 18-20	YES
	Claims	1-10, 15, 17	NO
Industrial applicability (IA)	Claims	1-20	YES
	Claims		NO
<b>2 Citations and explanations (Rule 70.7)</b>			
<p>The subject matter of claims 1-20 is novel over the prior art (PCT Article 33(2)) in light of the documents cited in the international search report.</p> <p>The problem addressed by the present invention appears to be that of providing an alternative process for producing micropellets. However, in light of the prior art the proposed process does not appear to involve an inventive step, since, compared to other granulation methods, spray granulation is a well-known process for preparing compositions of sparingly soluble active substances. Preparation of substances for granulation in the form of solid dispersions of micronized particles is likewise well known. The quantitative ratios shown also fall within the normal ranges for functional adjuvants and active substance. The list of solutizers in claim 4 is not limiting, since it is preceded by the expression "more particularly". The preferred macrolide antibiotics of the present application are explicitly mentioned among sparingly soluble active substances of the prior art (see EP1027887 (D1) paragraphs 18, 20, 23, 43, 45 and 73; WO02/089773 (D2) pages 16-17 and examples C and D). The process claimed in claims 1-10 and the micropellets or</p>			

## INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No.

PCT/EP2004/005993

Box No. V

Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability:  
citations and explanations supporting such statement

pharmaceutical presentations thereby obtainable claimed in claims 15 and 17 do not appear to involve an inventive step (PCT Article 33(3)) in light of D1 and D2.

The process claimed in claims 11-14 and the products claimed in claims 18-20 involve an inventive step, since the processes so restricted and the products thereby produced are not suggested by the prior art.

Expressions placed between parentheses in a claim can lead to lack of clarity, since it is not possible to discern whether said expressions have a restrictive effect on the subject matter of the claim in respect of novelty (claims 8, 15 and 16; PCT Article 6).